

Dishonesty in Medical Research and Publication and the Remedial Measures

The medical science has advanced at an extraordinary pace in the past 5–6 decades. Advances in medical science eliminated several communicable diseases, conquered majority infectious diseases, and controlled and modified many lifestyle-associated diseases. The growth achieved in various disciplines of medicine was through well-planned studies. The scientific journals spread new knowledge,^[1-4] push forward the frontiers of the current knowledge in every aspect,^[5-7] allow publication of creative ideas, and form the basis for ongoing innovations. The most notable Framingham Heart Study began in the town of Framingham, Massachusetts, in 1948 with 5209 cohorts and identified the common factors or characteristics that contribute to cardiovascular diseases^[8] and led to changes in day-to-day lifestyle and disease reduction. The broader aim of the medical research is to know what the truth is so that a correct or a most appropriate health care/management plan for a particular patient or for the community can be chosen with an objective to benefit patients and the society.^[9]

Academic institutions promote and support research by providing intramural grants; additionally, many government agencies including Indian Council of Medical Research, Department of Biotechnology funds research. Extramurally funded researches, innovations, and development of medical implants/prosthesis are considered more important and weighted higher. Federal grants for research are generally liberal for acclaimed researchers. The researcher is rewarded in many ways including career promotion, awards, acknowledgment among peers, and one-upmanship among colleagues and competitors. The notable medical developments/innovations commercialized are heart–lung machine, coronary and vascular stents; cochlear implant, imaging technologies, video-assisted surgery, ventilatory and circulatory support devices, *in vitro* fertilization techniques, laboratory equipment, and stem-cell banks. These medical advances are among the highly acclaimed achievements of the past century and were made possible by the research efforts of pure scientists, technologists, basic laboratory researchers, and clinicians. The clinician is the final link that delivers the fruits of research and development to the patients and society. These advances helped millions of patients worldwide. The researchers developing these innovations and molecules are acclaimed worldwide, and the manufacturers commercializing them made extraordinary monetary gains.

Apparently, to promote research, to recognize talent, and to reward researchers, Ministry of Health and Family Welfare, Government of India defined work standards for faculty of autonomous institutions of medical education in 2012 which

included publications for promotion under assessment promotion scheme.^[10] Similarly, in 2015, Medical Council of India made original research publication in indexed journals mandatory for appointment/promotion to various academic positions.^[11,12] Perhaps, the necessity of research publications for academic advances and promotions, peer pressure, lure of recognition, culture of “publish or perish,” and monetary benefits associated with benchmark research/development of new molecules/innovations perhaps resulted in the commercialization of research and fraud. Professional scientific paper writing and editing service are freely available, and many open access journals offer publication at a price.

Research papers have been flawed and retracted following disclosure of falsification/fabrication of data. Japanese anesthetist, Yoshitaka Fujii, infamously leads the world record with 190 retractions. From 1991 to 2011, he published prolifically and authored or co-authored around 250 articles in scientific and medical journals with an average of >12 publications per year over his career.^[13,14] More than half of these publications were randomized, double-blind, placebo-controlled trials, the “gold standard of evidence” for medical decision-making. Yoshitaka Fujii’s record of retractions shattered the record for retracted papers previously held by the German anesthetist Joachim Boldt, who briefly held this dubious distinction with 88 retracted articles.^[15] Robert (Bob) Slutsky, at the peak of his career, published one paper every 10 days, many of his papers have been retracted. He was one of the most prolific fraudsters in the history of cardiac research.^[16,17] Since 1975, there has been a 10-fold increase in scientific articles retracted due to fraud.^[18]

The pharmaceutical industry has also been shown to influence research integrity.^[19] Several molecules have been withdrawn from the market. The notables are paroxetine hydrochloride (Paxil), bupropion hydrochloride (Wellbutrin), and rosiglitazone maleate (Avandia), all the three molecules were developed by GlaxoSmithKline (GSK). In case of Avandia, GSK had masked the drug’s safety profile to protect sales.^[20-22] Thus, drug development, if driven by financial gains, has grave implications for the future of research and patient safety. The GSK had to pay \$3 billion following a criminal investigation by the US Department of Justice for failing to report safety data and for introducing “misbranded” drugs. The settlement is the largest for health-care fraud in the US history. In 1998, Andrew Wakefield and 12 of his colleagues suggested that the measles, mumps, and rubella (MMR) vaccine may predispose children to behavioral regression

and pervasive developmental disorder. Subsequent media involvement resulted in a significant drop in MMR vaccination rates, from 92% in 1997 to below 85% in 2002, with a rise in associated caseload.^[23] Later investigations revealed data manipulation and undeclared conflict of interest, with Wakefield having received £50,000 from a lawyer who headed a lawsuit against the MMR vaccine.^[24] The article was retracted and Wakefield was struck off by the General Medical Council in 2010.

In a systematic review, Ravnskov *et al.* reported a lack of an association or an inverse association between low-density-lipoprotein cholesterol and mortality in the elderly.^[25] Taylor *et al.* studied statins on primary prevention of cardiovascular diseases (CVD) and concluded, "Only limited evidence showed that primary prevention with statins may be cost effective and improve patient quality of life."^[26] US preventive services task force (USPSTF) in their recommendation has stratified the indications of statins based on age, risk factors, and a calculated 10-year CVD event risk, and the task force has rationalized and curtailed its use.^[27] Recently, the Indian government put a temporary ban on commercial banking of stem cells derived from biological materials such as cord tissue, placenta, tooth extract, and menstrual blood in the absence of scientific evidence about its benefits.

Apparently, the necessity of research publications for academic advances and promotions, the culture of "publish or perish," the monetary benefits, etc., associated with research resulted in fraud in research and commercialization of research. Every profession will have some dishonest people. In majority of research frauds, colleagues in the department, co-authors, and many other people in the hospital probably knew or suspected that the researcher was making up the data. The concern is not that some doctors and some researchers are dishonest; the main concern is that there is a failure to deal with the misconduct.^[28] The journal editors can at best retract a published article and recommend punitive action to the authors' institutional head. The laws are tougher in the United States of America as described above in case of GSK. However, in various institutes and countries, the Institute authority, the Institute Ethical Committees, the scientific societies, and the legal system do not have firm guidelines or measures to stop the practice. In the UK, a Committee on Publication Ethics was founded in 1997; however, until 2012, a body to spearhead the work in research misconduct was still lacking.^[29,30] A recent British Medical Journal survey showed that 13% of doctors claimed to have knowledge of data fabrication, with 6% claiming of being aware of cases of possible research misconduct at their institutions that had not been properly investigated.^[31]

The medical journalism is a highly responsible job. The fraudulent research results in scientists relying on the meaningless data and perhaps ends in altering

their own research plans as a consequence, and finally loss of valuable time of busy peer reviewers. The medical/surgical management of patients is based on the scientific data available in the Journals, textbooks, data presented in conferences, etc. The innocent patient is the recipient of medical/surgical treatment based on the false research and become the victim of the reasons that drive research including the desire of recognition among peers, the phenomenon of one-upmanship, and the industrial incentives.

Fraud in scientific publication has far-reaching consequences on patient care and cannot be taken as simple crime. They are crimes against humanity and thus the regulatory authorities should award an exemplary punishment. Institutional heads should develop mechanisms to address the issue of fraudulent research as prevailing in the USA and need to take strict punitive action against the authors of such fraudulent publication. Departmental enquiry should be initiated to investigate the falsification and the strictures awarded should be recorded in the professional career record of the author(s). The authors should ensure that the material submitted to the journal for publication is true to the best of their knowledge and is based on scientific data, and the reviewers and the editors should put all efforts to ensure that only scientific material based on evidences only finds a place in print. Editors must even be prepared to retract articles on their own, without the concurrence of the authors or their institutions. Finally, in this age of networking, the indexed journals can be networked by the field of interest or by taxonomy (keywords), and on retraction of an article, the editors and editorial websites of these journals automatically receive the title of the article and details of the authors of the retracted article and the editorial manager, in turn, block submission/acceptance of article of the authors involved in fraudulent research.

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